

OCT 14 2005

K050265

11. 510(k) Summary

Device: Model 700 – Chrono-log Whole Blood Lumi-Aggregometer

Date: February 3, 2005

Submitted by: Chrono-log Corp., 2 West Park Rd., Havertown, PA 19083

Contact: Nicholas J. Veriabo (610) 853-1130

Name of Device:

Trade/Proprietary Name - Model 700 Chrono-log Whole Blood
Lumi-Aggregometer

Common/Usual Name - Chrono-log Whole Blood Lumi-Aggregometer

Classification Name - System, Automatic Platelet Aggregation

After examining the test data included in this application, we have found the Chrono-log Model 700 Whole Blood Lumi-Aggregometer to be substantially equivalent to Chrono-log Model 560 Whole Blood Lumi-Aggregometer (K830749) with AGGRO/LINK Interface (K851025).

11.1 Device Description:

The Chrono-log Model 700 Aggregometer measures platelet function on patient samples using electrical impedance in whole blood or optical density in plasma. The Model 700 Aggregometer has the capability to simultaneously measure ATP release with either method using luminescence. The Model 700 Aggregometer is also used to run the Ristocetin Cofactor Assay which is used to diagnose patients with von Willebrands disease. The instrument comes with a starter kit consisting of the following Chrono-log reagents and supplies: ADP, Arachonic Acid, Collagen, Epinephrine, Ristocetin, Thrombin, a CHRONO-LUME® Kit, a Ristocetin Cofactor Kit, cuvettes, stir bars and pipettes. The output of the Model 700 can be connected to either a strip chart recorder or to a Computer. Software is provided the computer interface option. The computer interface option is used to collect data only. The computer is not used for diagnosis or treatment and does not have any control over or input into the Model 700 Aggregometer.

11.2 Intended Use:

For in-vitro diagnostic use for measuring platelet aggregation and ATP secretion in whole blood or platelet rich plasma.

11.3 Technical Description:

The Chrono-log Model 700 Aggregometer is an Instrument used in the Laboratory for the determination of Platelet Aggregation in samples of either PRP or whole blood specimens with simultaneous measurement of ATP release. For this application, the Model 700 is claiming substantial equivalency to the Chrono-log Corporation's Model 560 Aggregometer (K830749) with the Model 810 AGGRO/LINK (K851025) computer interface option currently in commercial distribution by Chrono-log Corp. The Model 700 has the ability to use the Chrono-log Disposable electrodes for which we demonstrate substantial equivalency to the Chrono-log Model 591A/592A (K032951) also currently in commercial distribution by Chrono-log Corporation.

The Model 700 Aggregometer uses many of the same parts as the Model 560 such as: Heater Blocks that hold the samples, LED and Photodiode circuit boards that measure changes in optical density for turbidometric aggregation, Impedance Electrodes used for impedance measurements in whole blood, Photomultiplier Tubes for measuring ATP release and stirring motors for sample stirring. The circuitry that connects to the measuring devices has been changed to more modern circuits. Provisions have been made so that the printed circuit boards for computer interface option can be placed inside the Aggregometer rather than be housed in a stand alone unit.

The chassis has also been redesigned and the front panel is improved with a Liquid Crystal Display (LCD) for displaying Temperature, Stirring Speed and Gain. The new front panel controls are tactile membrane switches. The chassis itself is shaped differently and has the ability for two units to interface together into a four channel configuration.

The output of the Model 700 series can be connected to either a strip chart recorder or to a Computer. Chrono-log provides software for the computer interface option as an accessory. The computer interface option is used to collect data and is not used for diagnosis or treatment and does not have any control over or input into the Model 700 Aggregometer.

11.4 Performance:

Comparison studies were run to compare the performance of the Model 700 to the Model 560 and the Model 591A for the disposable electrodes. Whole blood and Platelet Rich Plasma samples from normal, healthy, drug free subjects were tested with both instruments. The samples were tested using Chrono-log Collagen, ADP, Ristocetin, Epinephrine, Arachidonic Acid and Thrombin Reagents. The simultaneous measurement of ATP release was also measured using the luminescence technique. For ATP measurement CHRONO-LUME[®] was added to the sample.

The following concentrations of reagents were run: Collagen 2µg/mL and 5µg/mL, ADP 5µM and 10µM, Arachidonic Acid 0.5 mM, Epinephrine 5µM in PRP aggregation only, Ristocetin 1.0mg/mL for Whole Blood Aggregation and 1.25 mg/mL for PRP Aggregation and Thrombin for Luminescence measurement.

In Platelet Rich Plasma there were 149 comparison tests using optical aggregation with 167 Luminescence tests. In Whole Blood there were 267 comparison tests with Impedance Aggregation with 300 Luminescence tests. Although Aggregation and Luminescence are run simultaneously, there are always more Luminescence tests, because Aggregation is not measured with the thrombin reagent. At the recommended concentration, thrombin causes the platelets to clump in a single mass, which does not provide useful aggregation information. Thrombin at 1 unit concentration is used to measure the total amount of ATP in the platelets by Luminescence.

The Tables below show the correlation between the Model 700 and the Model 560

TABLE 9-1 Optical Aggregation in PRP

No. of Samples	Pearson correlation coefficient	P-value
149	0.8204	< 0.0001

TABLE 9-2 ATP Release by Luminescence in PRP

No. of Samples	Pearson correlation coefficient	P-value
167	0.6526	< 0.0001

TABLE 9-3 Impedance Aggregation in Whole Blood

No. of Samples	Pearson correlation coefficient	P-value
267	0.7798	< 0.0001

TABLE 9-4 ATP Release by Luminescence in Whole Blood

No. of Samples	Pearson correlation coefficient	P-value
300	0.7244	< 0.0001

Also, we conducted a comparison of the Model 700 to the to the Model 591A/592A using disposable electrodes. Below is a table comparing the results.

DISPOSABLE ELECTRODE COMPARISON		
REAGENT	700	592A
ADP 5	14	9
ADP 10	10	13
Collagen 2	18	14
Collagen 5	15	17
Risto .4	14	8
Risto .4	26	27
Risto .15	4	6
Risto .15	1	2

The results of both instruments are within the normal range as shown in the model 591A/592A Instruction Manual.

The results of our validation study, demonstrates that the Model 700 and the Model 560 are substantially equivalent devices. We further demonstrate that when disposable Electrodes are used in the Model 700, the results are substantially equivalent to the results of the Model 591A/592A..



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 14 2005

Mr. Nicholas J. Veriabo
Executive Director
Chrono-Log Corporation
2 West Park Road
Havertown, Pennsylvania 19083-4691

Re: k050265
Trade/Device Name: Chrono-Log Model 700 Whole Blood Lumi-Aggregometer
Regulation Number: 21 CFR § 864.5700
Regulation Name: Automated platelet aggregation system
Regulatory Class: II
Product Code: JOZ
Dated: September 2, 2005
Received: September 7, 2005

Dear Mr. Veriabo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in cursive script, reading "Robert L. Becker, Jr.", written in dark ink.

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

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Chrono-log Model 700 Whole Blood Lumi-Aggregometer

Indications For Use:

For in-vitro diagnostic use for measuring platelet aggregation and ATP secretion in whole blood or platelet rich plasma.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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